September 8, 2020

House Insurance Committee
Members of the House Insurance Committee
Attention Committee Clerk
Sergio Cavazos
Delivered via email: Sergio.Cavazos_HC@house.texas.gov

RE: HB 2536 – An Act Relating to Transparency Related to Drug Costs Interim Charge

Dear Chairman Lucio and Members of House Insurance Committee:

The Pharmaceutical Care Management Association (PCMA) appreciates your interest in one of the most critical issues facing policy makers today, the rising costs of prescription drugs. Please accept our response to your RFI regarding the implementation of HB 2536, which requires reporting by drug manufacturers, pharmacy benefit managers, and health insurers regarding pharmaceutical practices, including the pricing and availability of insulin.

PCMA is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, and other programs. According to researchers, PBMs hired by plan sponsors to maximize the value of prescription drug benefits, save patients and payers an average of $962 per person per year. [i] For every $1 spent on their services, PBMs reduce costs by $10[ii]. Plan sponsors use these savings to benefit patients by lowering premiums or deductibles.

HB2536 Overview and Implementation

The Houston Chronicle heralded HB2536 as one of the "toughest drug pricing bills" in the nation. HB2536 requires manufacturers to report a drug's wholesale acquisition cost and any price increases of at least 15% within one calendar year and price increases of 40% over three calendar years. They must also report aggregate company level research and development for the most recent year and the names of any drugs that lost patent exclusivity over the past three years. In addition, the health plan must report the 25 most-frequently prescribed drugs, increases in annual drug spending, and premium increases attributable to drugs. And finally, the PBM must report aggregated rebates, fees, and price protection payments collected from the pharmaceutical drug manufacturer.

While the Texas Health and Human Services website provides a clear outline of the requirements for manufacturers under HB2536, there has been a delay on behalf of the

manufacturers in submitting the information to the agency and there appears to be gaps in the information submitted. Implementing all requirements of HB 2536 as directed by the Legislature should occur to reach the legislation's goals of improving transparency around drug pricing.

Rebate Pricing

As further background on rebate pricing. Operating in a competitive environment, PBMs reduce brand drug costs primarily using manufacturer rebates. As part of manufacturer-PBM negotiations, brand drug manufacturers compete for formulary placement by offering rebates for moving market share, which are typically calculated and paid weeks or months after a drug is dispensed. As a result of these negotiations, PBMs can recommend benefit designs that stretch payers' finite dollars and reduce premiums and cost-sharing. These designs include cost-sharing incentives for patients to use the most affordable drugs, which often are generics. The highest cost-sharing is typically reserved for drugs with the least competitive price concessions, or in the case of many high-priced, single-source drugs, no price concessions at all.

Studies have shown that rebates lower government costs and lead to lower premiums for plan enrollees.[iii] The rebate system that prevails today was largely shaped by a series of private antitrust lawsuits brought in the 1990s by pharmacies against brand drug manufacturers.[iv] These cases were consolidated in a federal antitrust class action, *In re Brand Name Prescription Drugs Antitrust Litigation.*

It is always the drug manufacturer who decides what the price of a given drug will be. PBMs do not set drug prices—rather, PBMs lower the cost of drug benefits by negotiating price concessions with manufacturers and pharmacies on behalf of our clients. A competitive marketplace, where drug manufacturers are forced to compete is the most valuable tool for driving down the cost of prescription medications.

Insulin Pricing

Recent CDC studies suggest that over 34 million Americans suffer from diabetes[v], while in Texas over 2.5 million adults[vi] have been diagnosed, a dramatic 40% increase over the past 10 years. During that same decade, insulin prices have dramatically escalated. This is due to the fact that there are only three drug manufacturers who control the entire market, the lack of alternative insulins, and manufacturer abuse of patent extensions.

PBMs drive competition using drug formularies and rebates. In spite of dramatic increases in list prices with **total gross sales** increasing from **$22B in 2012 to $54B** in 2019, **net costs have been flat** with total net sales of **$13B in 2012 and remained the same $13B**[vii] in 2019 due to PBM-negotiated rebates, statutory rebates, and other manufacturer discounts. PBMs are creating innovative programs that limit consumer out-of-pocket (OOP) insulin costs, to promote affordable access, as well as clinical programs that improve care and patient outcomes.

As stated above, historically three manufacturers have made all of the insulin in the

United States: Eli Lilly, Novo Nordisk, and Sanofi. Manufacturers utilize the patent system as a way to prolong market exclusivity. These additional patents are often for incremental improvements such as delivery mechanisms (e.g., insulin pens) and alternative formulations (e.g., multi-drug combination products).

With only three manufacturers, competition has been very limited; thus, leading to uninhibited price increases. Manufacturer list prices have increased in lock-step with one another.

The lack of competition has led to a drastic increase in both list and launch prices of insulins. Insulin list prices have increased more than tenfold since 1985.

- Prices for Humulin/Novolin have increased from approximately $25 per prescription in 1985 to $400+ in 2019.
- Prices for long-acting insulins have increased from about $100 per prescription in 2007 to $425+ in 2019.

During the past 20 years, new insulins have entered the market, but almost always at higher prices than the existing products. One exception was Basaglar, introduced in December 2016. It was the first follow-on long-acting insulin[viii].

The unfettered price increases of prescription drugs put patients at risk and health plan sponsors in the difficult position of either having to cut benefits or increase premiums, copays and deductibles. Copay caps, often seen as a public policy solution to the rising costs of prescription drugs, are simply a government-set price insulation that benefit brand drug manufacturers at the expense of patients and employers. And those individuals and families that are uninsured or have a high deductible health plan are the ones most affected by the manufacturers unfettered price increases and not protected by copay caps. These mandates prevent payers from effectively managing drug costs and force the public to pay more in health premiums and overall health care costs.

PCMA and our member companies continue to work to reduce the costs of insulin for payers and patients. I am attaching a recent study, “Insulins: Managing Costs With Increasing Manufacturer Prices” prepared by Visante on behalf of PCMA.

On behalf of PCMA I appreciate the opportunity to offer a response to the RFI on HB 2536 and would be happy to answer any questions. I can be reached at 270-454-1773. Thank you for your consideration.

Sincerely,

Melodie Shrader
Associate Vice President, State Affairs

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[i] Visante, Inc., *"The Return on Investment (ROI) on PBM Services," Prepared for PCMA, February 2020. https://www.pcmanet.org/wp-content/uploads/2020/02/ROI-on-PBM-Services-FINAL_.pdf*

[ii] *Ibid*

[iii] U.S. Government Accountability Office report: "Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization," July, 2019 https://www.gao.gov/assets/710/700259.pdf and U.S. Dept. of Health & Human Services, Office of Inspector General, "Rebates for Brand-Name Drugs in Part D Substantially Reduced the Growth in Spending from 2011 to 2015," September, 2019 https://oig.hhs.gov/oei/reports/oei-03-19-00010.pdf

[iv] *In Re Brand Name Prescription Drugs Antitrust Litigation,* 94 C 897, MDL 997 (N. D. Ill. 1994).

[v] CDC National Diabetes Statistics Report for 2020, https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

[vi] *Texas Diabetes Council State Plan for Diabetes and Obesity Treatment, November 2019,* file:///C:/Users/mshrader/Downloads/2019%20State%20Plan%20for%20Diabetes%20and%20Obesity%20Treatment%20and%20Education.pdf

[vii] *Visante Inc., "Insulins: Managing Costs with Increasing Manufacturer Prices," Prepared for PCMA, August 2020.* https://www.pcmanet.org/wp-content/uploads/2020/08/PCMA_Visante-Insulins-Prices-and-Costs-.pdf

[viii] *Ibid. page 4*

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